27130. Misbranding of thyroid tablets. U. S. v. Armour & Co., a corporation. Plea of nolo contendere. Fine, $25 and costs. (F. & D. no. 36089. Sample nos. 28392–B, 28393–B.)

These tablets contained thyroid powder U. S. P. in excess of the quantity stated on the label. The ¼-grain tablets contained not less than ⅖ grain of thyroid powder U. S. P., and the 1/10-grain tablets contained not less than ⅛ grain and ⅓ grain of thyroid powder U. S. P.

On April 22, 1936, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Armour & Co., Chicago, Ill., charging shipment by said corporation in violation of the Food and Drugs Act on or about February 23 and March 11, 1935, from the State of Illinois into the State of Texas of quantities of thyroid tablets that were misbranded.

The article in the first of the two consignments was alleged to be misbranded in that the statement "Thyroid Tablets ¼ Grain", borne on the cartons enclosing the bottles, and the statement "Thyroid Tablets * * * Each Tablet Contains ¼ Grain Thyroid Powder U. S. P." borne on the bottle labels, were false and misleading in that they represented that each of the tablets contained ¼ grain of thyroid, and that each of the tablets contained ¼ grain of thyroid powder U. S. P. having 0.2 percent iodin in thyroid combination; whereas in fact each of the tablets contained more than ¼ grain, namely, not less than ⅖ grain of thyroid, and each of the tablets contained more than ¼ grain of thyroid powder U. S. P. having $.2 percent iodin in thyroid combination.

The article in the second of the two consignments was alleged to be misbranded in that the statement "Thyroid Tablets 1/10 Grain", borne on the cartons and the statement, "Thyroid Tablets * * * Each Tablet Contains 1/10 Grain Thyroid Powder U. S. P.", borne on the bottle labels, were false and misleading in that they represented that each of the tablets contained 1/10 grain of thyroid, and that each of the tablets contained 1/10 grain of thyroid powder U. S. P.; whereas in fact each of the tablets contained more than 1/10 grain of thyroid, and each of the tablets contained more than 1/10 grain of thyroid powder U. S. P.

On June 26, 1936, a motion to quash the information was filed on behalf of the defendant corporation. On December 23, 1936, the court denied the motion to quash in an opinion as follows:

SULLIVAN, *District Judge*: This case involves the interstate shipment by Armour & Company of thyroid tablets which the Government alleges are adulterated and misbranded, the theory being that the tablets contain a greater amount of thyroid powder than is indicated on the label, thus constituting adulteration and misbranding within the meaning of Sec. 7 and Sec. 8 of the Act of June 30, 1906, known as the Food and Drugs Act. (USCA Title 21, Sections 8 and 9.)

The information as amended contains four counts, counts I and III charging adulteration, and counts II and IV charging misbranding.

On the adulteration charge the information alleges that the bottles containing the tablets bear the following label: "100 Thyroid Tablets, ¼ grain. Each Tablet contains ¼ grain thyroid powder U. S. P. having 0.2 per cent iodin in thyroid combination."

Count I of the information then goes on to allege that the said article of drugs was adulterated: "In that its strength and purity fell below the professed standard and quality under which it was sold, in that each of said tablets was represented to contain ¼ grain of thyroid powder U. S. P., having 0.2 percent iodin in thyroid combination; whereas in truth and in fact each of said tablets contained more than ¼ grain thyroid powder U. S. P., having 0.2 percent iodin in thyroid combination."

Count III is the same as count I, except that it refers to tablets represented as containing 1/10 grain of thyroid powder U. S. P., having 0.2 percent iodin in thyroid combination; whereas in fact each of said tablets contains more than 1/10 grain.

As to the misbranding charge, the information alleges, (count II) "That said article of drugs, when shipped and delivered for shipment as aforesaid, was then and there misbranded within the meaning of said Act of Congress, in that the statements, to wit, "Thyroid tablets ¼ grain" borne on the cartons as aforesaid, and "Thyroid tablets ¼ grain, each tablet contains ¼ grain thyroid powder U. S. P. having 0.2 percent iodin in Thyroid combination," borne on the label attached to the bottles containing the article, as aforesaid, regarding the article, and the substance contained therein, were false and misleading in

this, that they represented that each of said tablets contained ¼ grain of thyroid, and that each of said tablets contained ¼ grain of thyroid powder U. S. P., having 0.2 percent iodin in thyroid combination; whereas in truth and in fact, each of said tablets contained more than ¼ grain of thyroid, and each of said tablets contained more than ¼ grain of thyroid powder U. S. P., having 0.2 percent iodin in thyroid combination."

Count IV is identical, except that the tablets therein referred to were represented to contain $\frac{1}{10}$ grain thyroid powder. The case is now before me on defendant's motion to quash the Amended Information. Section 7, Par. 2 of the Food and Drugs Act (Sec. 8, Title 21 USCA) provides: "That for the purposes of this Act an article shall be deemed to be adulterated: In case of drugs: * * * Second. If its strength or purity falls below the professed standard or quality under which it is sold."

Defendant sets out that the Eleventh Decennial Revision of the Pharmacopoeia of the United States, published by authority of the United States Pharmacopoeia Convention held in 1930, and which has not been superseded by any subsequent edition, does not define Thyroid powder, but does define Thyroideum (thyroid).

The Government contends that the Pharmacopoeia involved is the Tenth Revision rather than the Eleventh, but admits that the standard for thyroid set up in both is identical.

Defendant urges that there is no claim in the information that the thyroid contained in the thyroid powder fails to comply with the standard set forth in the United States Pharmacopoeia, but only that its strength and purity fell below the professed standard and quality under which it was sold. That thyroid powder is the subject of the sale and shipment, and if the thyroid contains "0.2 per cent iodin in thyroid combination" as stated on the label, because that is the only claim made as to strength, purity, or quality, then there is no adulteration. That the fact that it contains an excess of the amount claimed on the label is not a false or misleading statement within the meaning of the Food and Drugs Act, unless it is shown that the buyer is injured thereby.

On this question the Government takes the position that an excessive amount of thyroid, which the Information charges these tablets contain—as well as a deficiency thereof—should be construed as falling below the professed standard, as set out on the label, thereby constituting adulteration under the Statute.

In the case of *George A. Breon & Co.*, vs. *United States*, 74 Fed. (2) 4, cited by defendant in its reply brief, one of the questions involved was whether or not the Adulteration Section of the Statute covered drugs containing an excess of any ingredient (in that case dessicated thyroid) as well as those where strength or purity fall below the professed standard or quality under which it was sold. Commenting on this phase of the case the court said: "In the view we have taken of the other issues involved however, we do not deem it necessary to pass upon this question." In the case of *United States* vs. *Resnick, et al.*, and *United States* vs. *Acme Can Company*, decided by the Supreme Court of the United States on December 7, 1936, defendants were indicted for violation of the Standard Container Act, on the ground that they sold two quart metal hampers which did not comply with the Act, in that they were not of any standard size authorized by the Act, which defined various sized hampers, but did not include two quart metal hampers. Defendants demurred on the ground that the facts alleged were not sufficient to constitute a violation of the Act. The trial court sustained the demurrers and discharged defendants, and the United States appealed. The Supreme Court in passing on the case said: "It follows that unless the clause of section 5 which forbids manufacture or sale of containers 'that do not comply with this Act' makes criminal the manufacture or sale of two-quart hampers, the facts alleged do not constitute any defense. Statutes creating crimes are to be strictly construed in favor of the accused; they may not be held to extend to cases not covered by the words used. *United States* v. *Wiltberger*, 5 Wheat. 76. *Fasulo* v. *United States*, 272 U. S. 620. The clause (5) just quoted is crucial; its words are plain and having regard to the connection in which they are used, must be given the meaning naturally attributable to them. It is obvious that they do not extend to hampers other than the nine classes defined in Section 1. The Act applies to none of capacity less than four quarts. * * * It expresses no con-

demnation of two-quart hampers. Before one may be punished, it must appear that his case is plainly within the statute; there are no constructive offenses." The judgment sustaining the demurrers was sustained.

Under the ruling in the above case I am of the opinion that the facts alleged in Counts I and III do not constitute adulteration, therefore the Motion to Quash as to Counts I and III will be allowed.

I now come to Counts II and IV which charge misbranding.

Section 8 of the Food and Drugs Act (Sec. 9 Title 21 USCA) provides: "That the term 'misbranded' as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular. * * *"

In *United States* vs. *Lexington Mill & Elevator Company*, 232 U. S., 399, the court said: "The statute upon its face shows that the primary purpose of Congress was to prevent injury to the public by the sale and transportation in interstate commerce of misbranded and adulterated foods. The legislation against misbranding intended to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was, and not upon misrepresentations as to character and quality."

The Food and Drugs Act was passed for the purpose of protecting the general public, to preserve their health and to prevent their being deceived by label or brand as to the real character of the article offered for sale. *United States* vs. *95 Barrels of Vinegar*, 265 U. S. 438.

Again in the case of *United States* vs. *95 Barrels of Vinegar, supra*, the court said: "The statute is plain and direct. Its comprehensive terms condenmn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act. * * * If an article is not the identical thing that the brand indicates it to be, it is misbranded."

It is agreed that the tablets here in question contain thyroid, a more or less powerful drug used in the treatment of certain diseases. These tablets are susceptible of analysis to determine just what ingredients and how much of each they do contain, in order that they may be accurately labeled.

I am of the opinion that a drug being here involved, the Act requires a correct statement thereof on the label.

The Motion to Quash as to Counts II and IV is denied, and defendant is given ten days in which to plead.

On February 25, 1937, a plea of nolo contendere was entered on behalf of the defendant corporation and the court imposed a fine of $25 and costs.

HARRY L. BROWN,
Acting Secretary of Agriculture.

27131. Adulteration and misbranding of tincture nux vomica U. S. P. U. S. v. Endo Products, Inc. Plea of guilty. Fine, $100. (F. & D. no. 37925. Sample no. 50523–B.)

This product differed from the standard prescribed for nux vomica in the United States Pharmacopoeia and contained a smaller proportion of the aklaloids of mux vomica than that represented on the label.

On March 1, 1937, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Endo Products Co., Inc., New York, N. Y., charging shipment by said corporation in violation of the Food and Drugs Act, on or about December 5, 1935, from the State of New York into the State of New Jersey of a quantity of an article, labeled "Tincture Nux Vomica U. S. P.", which was adulterated and misbranded.

It was alleged to be adulterated in that it was sold under and by a name recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the test laid down in said pharmacopoeia in that it yielded less than 0.237 gram, to wit, not more than